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Stephen J. Brown

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EXAMINER

RANGREJ, SHEETAL

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,107	<b>Applicant(s)</b> BROWN, STEPHEN J.	
	<b>Examiner</b> SHEETAL R. RANGREJ	<b>Art Unit</b> 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Prosecution History Summary***

- Claims 1, 9, 17, 19, 27-28, 34, 40, 49-50, and 59 are amended.
- Claims 1-59 are pending.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/02/2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckers (U.S. Patent No. 5,019,974).

3. As per claim 1, Beckers teaches a blood glucose monitoring system, comprising:
  - a. a blood glucose monitor for monitoring a blood glucose level and for producing digitally

encoded blood glucose level signals representative of said blood glucose level (**Beckers: col. 6, 63-col. 8, 14**);

b. a programmable microprocessor-based portable unit that is separate from the blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video display for displaying information, said video display configured to display graphic and alphanumeric information, 2) a plurality of switches operable for interactively controlling said programmable microprocessor based portable unit and for manipulating the information displayed on said video display, and 3) a circuit coupled to said plurality of switches for generating video signals in response to the operation of the switches (**Beckers: col. 2, 27-37; col. 6, 63-col. 8, 14; figure 1**);

c. a digital data storage medium, the medium

A. readable by said programmable microprocessor-based portable unit (**Beckers: col. 2, 27-37**); and

B. tangibly embodying therein a program of instructions executable by said programmable microprocessor-based portable unit, said program of instructions including instructions for signal processing in response to signals generated based upon said digitally encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage (**Beckers: col. 2, 27-37; col. 3, 38-50**);

d. a signal interface connected in signal communication with said programmable microprocessor-based portable unit and said blood glucose monitor for coupling said digitally encoded blood glucose level signals supplied by said blood glucose monitor to said programmable microprocessor-based portable unit (**Beckers: col. 11, 12-19**); and

e. signal processing means connected in signal communication with said signal interface for performing signal processing functions in accordance with said program of instructions  
**(Beckers: col. 11, 12-19).**

It would have been obvious to modify the teachings of Beckers with the motivation of providing a system for patients with diabetes to track the changes made in health due to changing age or daily routine **(Beckers: col. 1, 19-29).**

4. As per claim 2, Beckers teaches wherein said microprocessor-based portable unit is a palm-top computer **(Beckers: figure 1).**

The motivation to modify is the same as claim 1.

5. As per claim 3, Beckers teaches the blood glucose monitor for receiving a test strip including a reagent impregnated portion having blood applied thereto **(Beckers: col. 6, 19-36).**

The motivation to modify is the same as claim 1.

6. As per claim 8, Beckers teaches at least a component of said signal interface being connectable with a second device, other than said blood glucose monitor, in signal communication with said programmable microprocessor-based portable unit for coupling further signals supplied by said second device to said programmable microprocessor-based portable unit **(Beckers: claim 12(a)).**

The motivation to modify is the same as claim 1.

7. As per claim 9, Beckers teaches wherein said programmable microprocessor-based portable unit comprises an interactive interface **(Beckers: figure 1).**

The motivation to modify is the same as claim 1.

8. As per claim 17, Beckers teaches A method of performing diabetes self-care with a system of integrated electronic devices, comprising:

-powering a portable blood glucose monitor with one or more batteries (**Beckers: col. 6, 19-22; col. 8, 16-22**);

-receiving an amount of blood sufficient for a blood glucose monitor to run a blood glucose test sequence (**Beckers: col. 6, 23-27**);

-controlling the blood glucose test sequence (**Beckers: col. 6, 19-36**);

-computing a blood glucose level (**Beckers: col. 6, 34-36**);

-signal coupling the blood glucose monitor to a portable microprocessor-based electronic device via a first data port, wherein said portable microprocessor-based electronic device is separate from the blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video display for displaying information, said video display configured to display graphic and alphanumeric information, 2) a plurality of switches operable for interactively controlling said programmable microprocessor based portable unit and for manipulating the information displayed on said video display, and 3) a circuit coupled to said plurality of switches for generating video signals in response to the operation of the switches (**Beckers: col. 2, 27-37; col. 6, 63-col. 8, 14; figure 1**);

-transmitting blood glucose test results from said blood glucose monitor to said portable microprocessor-based electronic device (**Beckers: col. 2, 34-37**);

-running program instructions stored in a memory of the portable microprocessor- based electronic device for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage (**Beckers: col. 2, 27-53**);

and

-recording blood glucose test results and insulin dosage information in said memory of the portable microprocessor-based electronic device, said memory also containing programming for establishing a data protocol that allows digital data signal processing, and for performing said analysis of blood glucose (**Beckers: col. 2, 27-53**).

The motivation to modify is the same as claim 1.

9. As per claim 18, Beckers teaches the receiving including inserting a test strip into a receptacle of the blood glucose monitor; and applying a drop of blood to the strip (**Beckers: col. 6, 23-27**).

The motivation to modify is the same as claim 1.

10. As per claim 19, Beckers teaches further comprising displaying the blood glucose level on said video display (**Beckers: col. 6, 34-36; figure 2**).

The motivation to modify is the same as claim 1.

11. As per claim 27, Beckers teaches wherein said portable microprocessor-based electronic device further comprises an interactive interface and said plurality of switches includes a pair of spaced-apart push button switches and another pair of switches (**Beckers: figure 1**).

The motivation to modify is the same as claim 1.

12. As per claim 28, Beckers teaches a blood glucose monitoring system, comprising:  
a. a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level (**Beckers: col. 6, 63-col. 8, 14**);

- b. a programmable microprocessor-based portable unit that is separate from the blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video display for displaying information, said video display configured to display graphic and alphanumeric information, 2) a plurality of switches operable for interactively controlling said programmable microprocessor based portable unit and for manipulating the information displayed on said video display, and 3) a circuit coupled to said plurality of switches for generating video signals in response to the operation of the switches (**Beckers: col. 2, 27-37; col. 6, 63-col. 8, 14; figure 1**);
- c. digital data storage media tangibly embodying therein processor-executable program instructions for signal processing in response to signals based upon said digitally encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage and further for performing a test sequence to confirm that the system is operating properly (**Beckers: col. 3, 23-50**);
- d. a signal interface connected in signal communication with said programmable microprocessor-based portable unit and said blood glucose monitor for coupling said digitally encoded health signals supplied by said blood glucose monitor to said programmable microprocessor-based portable unit (**Beckers: col. 11, 12-19**); and
- e. signal processing means connected in signal communication with said signal interface for performing signal processing functions in accordance with said program of instructions (**Beckers: col. 11, 12-19**).

The motivation to modify is the same as claim 1.

13. As per claim 40, Beckers teaches A system of interconnected devices for performing diabetes self-care, comprising:



(a) a blood glucose monitor, including:

(i) a receptacle for receiving an amount of blood sufficient for the monitor to run a blood glucose test sequence **(Beckers: col. 6, 24-27)**;

(ii) processing circuitry for controlling a blood glucose test sequence and computing a blood glucose level **(Beckers: col. 6, 28-36)**,

(iii) a battery compartment for holding a battery for powering the blood glucose monitor **(Beckers: col. 8, 16-22)**, and

(iv) a first data port for signal coupling to another electronic device **(Beckers: col. 10, 30-32)**; and

(b) a portable microprocessor-based device that is separate from the blood glucose monitor and signal coupled with the blood glucose monitor, including:

(i) a second data port for signal coupling with the first data port and receiving blood glucose test results from said blood glucose monitor **(Beckers: col. 9, 25-30)**,

(ii) a microprocessor that runs according to program instructions stored in a memory for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage **(Beckers: col. 3, 38-50)**,

(iii) a memory for recording the recorded blood glucose test results and insulin dosage information therein, and for containing programming for establishing a data protocol that allows digital data signal processing, and for performing analysis of blood glucose test results, **(Beckers: col. 3, 38-50)**.

(iv) a video display for displaying information, said video display configured to display graphic and alphanumeric information,

(v) a plurality of switches operable for interactively controlling said programmable microprocessor based portable unit and for manipulating the information displayed on said video display, and

(vi) a circuit coupled to said plurality of switches for generating video signals in response to the operation of the switches (Beckers: col. 2, 27-37; col. 6, 63-col. 8, 14; figure 1)

The motivation to modify is the same as claim 1.

14. Claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-48, 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckers (U.S. Patent No. 5,019,974) in view of Reference U.

15. As per claim 4, Beckers does not explicitly teach the program of instructions including instructions for monitoring whether a sufficient amount of blood has been applied to said reagent impregnated portion of the test strip.

Reference U teaches the program of instructions including instructions for monitoring whether a sufficient amount of blood has been applied to said reagent impregnated portion of the test strip (**U: p. 253, col. 2, para. 5**).

It would have been obvious to one of ordinary skill in the art to combine the teachings with the motivation of giving the patients a greater responsibility for managing their diabetes (**U: p. 253, col. 1, para. 1**).

16. As per claim 5, Beckers does not explicitly teach the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor.

Reference U teaches the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor (**U: p. 265, col. 2, para. 3**).

The motivation to combine the teachings is the same as claim 4.

17. As per claim 6, Beckers does not explicitly teach the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor.

Reference U teaches the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor (**U: p. 257, col. 1, para. 2**).

The motivation to combine the teachings is the same as claim 4.

18. As per claim 7, Beckers does not explicitly teach the program of instructions further including instructions for performing a test sequence to confirm that the system is operating properly.

Reference U teaches the program of instructions further including instructions for performing a test sequence to confirm that the system is operating properly (**U: p. 257, col. 1, para. 2**).

The motivation to combine the teachings is the same as claim 4.

19. Claims 10-16 recite substantially similar limitations as those already addressed in claims 2-8, and, as such, are rejected for similar reasons as given above.

20. Claims 20-26 recite substantially similar limitations as those already addressed in claims 2-8, and, as such, are rejected for similar reasons as given above.

21. Claims 29-31 recite substantially similar limitations as those already addressed in claims 3-5, and, as such, are rejected for similar reasons as given above.

22. Claim 32 recite substantially similar limitations as those already addressed in claim 2, and, as such, are rejected for similar reasons as given above.

23. Claims 33-34 recite substantially similar limitations as those already addressed in claims 8-9, and, as such, are rejected for similar reasons as given above.

24. Claims 35-38 recite substantially similar limitations as those already addressed in claims 2-5, and, as such, are rejected for similar reasons as given above.

25. Claim 39 recite substantially similar limitations as those already addressed in claim 8, and, as such, are rejected for similar reasons as given above.

26. Claims 41-42 recite substantially similar limitations as those already addressed in claims 18-19, and, as such, are rejected for similar reasons as given above.

27. Claims 43-50 recite substantially similar limitations as those already addressed in claims 2-9, and, as such, are rejected for similar reasons as given above.

28. Claims 51-52 recite substantially similar limitations as those already addressed in claims 18-19, and, as such, are rejected for similar reasons as given above.

29. Claims 53-59 recite substantially similar limitations as those already addressed in claims 2-8, and, as such, are rejected for similar reasons as given above.

### ***Response to Arguments***

30. Applicant's arguments filed for claims 1-59 have been fully considered but they are not persuasive.

31. Applicant argues that the blood glucose test strip reader of Beckers is not separate from the recorder of Beckers. Examiner states that to make something separable does not render the claim non-obvious over the prior art (*In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) The claimed structure, a lipstick holder with a removable cap, was fully met by the

prior art except that in the prior art the cap is “press fitted” and therefore not manually removable. The court held that “if it were considered desirable for any reason to obtain access to the end of [the prior art’s] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.”).

32. Applicant states that Beckers was cited for similar reason in case no. 90/008,234 and a similar amendment overcame the rejections based on Beckers. Examiner states that the application does not disclose Beckers as overcoming the rejection but rather different prior arts, therefore Examiner maintains the rejections.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant’s disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jerry O’Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. R. R./  
Examiner, Art Unit 3686  
April 25, 2009

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
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